

Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

9310-28CT

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on **August 17, 2006**

Signature

Typed or printed name **Tracy Wallace**

Application Number

09/760,085

Filed

January 12, 2001

First Named Inventor

Goudsmit et al.

Art Unit

1637

Examiner

J. Tung

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐

applicant/inventor.

☐assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)☒attorney or agent of record. **40,142**
Registration number☐

attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34

Signature

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Typed or printed name

919-854-1400

Telephone number

August 17, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒*Total of **3** forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Attorney Docket No. 9310.28CT

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Goudsmit et al.

Confirmation No.: 3169

Application Serial No.: 09/760,085

Group Art Unit: 1637

Filed: January 12, 2001

Examiner: J. Tung

For: *ISOLATION AND AMPLIFICATION OF NUCLEIC ACID MATERIALS*

August 17, 2006

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

Sir:

This document is submitted in support of the Pre-Appeal Brief Request for Review filed concurrently herewith with a Notice of Appeal for the above-referenced patent application.

Claims 16-21, 28-31, 39-41 and 43 are pending in this application. Claims 16-21, 28-31, 39-41 and 43 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Bastian et al. This request notes the clear error in facts and/or the lack of elements needed for a *prima facie* rejection of these claims.

Specifically, although these claims were acknowledged by the Examiner and her supervisor to be allowable pursuant to a telephone interview on October 5, 2004, in which Examiner Tung, Examiner Horlick and Supervisory Examiner Benzion participated and for which a Notice of Allowance was issued on October 19, 2004, they are now rejected on the basis that the term "consisting essentially of" is being construed as equivalent to "comprising" and are thus allegedly anticipated by Bastian et al. Specifically, the Examiner states that if it is applicants' contention that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicants have "...the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicants' invention." (citing *In re De Lajarte*, 337 F3d 870; 143 USPQ 256 (CCPA 1964) and *Ex parte Hoffman* 12 USPQ2d 1061 (Bd. Pat. App. & Inter. 1989).

As discussed during the October 5, 2004 telephone interview, applicants direct the Examiners' attention to MPEP § 2111.03, wherein the phrase "consisting essentially of" is described as meaning that the scope of the claim is limited to the specified materials and "those that do not materially affect the basic and novel characteristics of the claimed invention." (citing *In re Hertz*). The term "consisting essentially of" occupies a middle ground between "consisting of" and "comprising." The Office Action disregards this distinction to state that "consisting essentially of" is the same as "comprising." This is incorrect, as it is clear that the "consisting essentially of" language is intended to occupy the middle ground of limiting the

scope of the claims to the specified materials and those that do not affect the basic and novel characteristics of the claimed invention.

Thus, in the context of the second liquid of the methods of this invention, this phrase is to be interpreted to mean that, in addition to the materials specifically recited in the claims, the liquid excludes materials such as alcohol groups, which do affect the functional capabilities of the liquid to facilitate binding of nucleic acid to a solid phase, but can include materials of this invention that do not affect the functional capabilities of the liquid to facilitate binding of nucleic acid to a solid phase. Such materials (e.g., Tris-HCl; Triton X-100; NaOH; H₂O) are described in the specification on page 7, lines 19-32.

In response to the Examiner's statement that the applicants must show that the introduction of additional components would materially change the characteristics of the claimed invention, applicants direct the Examiners' attention to the Bastian et al. reference cited in this rejection. In particular, the invention set forth in the Bastian et al. patent and corresponding PCT publication is based on the proposal by Bastian et al. that variations in the concentration of materials containing alcohol groups in a binding solution influenced the binding characteristics of single stranded nucleic acid or double stranded nucleic acid. Applicants refer the Examiner to column 4, lines 17-43, of the Bastian et al. patent, wherein it is stated:

FIG. 1 shows the binding of single-stranded/double-stranded nucleic acid exemplified by single-stranded RNA and double-stranded DNA. Described here is the RNA/DNA binding from a tissue lysate to a mineral support as a function of the concentration of a material containing alcohol groups (here, ethanol) and a chaotropic substance (here, GTC). Under the condition that the concentration of one of the substances, alcohol or chaotropic substance, is constant, it is found that at a high alcohol concentration and/or amount of chaotropic substance, both types of nucleic acid (RNA/DNA) are bound to the mineral support. If the concentration of one or both substances (alcohol or chaotropic substance) becomes less than a defined value, none of the nucleic acids will bind to the mineral support to any substantial extent. Surprisingly, in between, RNA and DNA will bind to the mineral support to such different extents as can be made use of for the separation of the nucleic acids. Thus, proceeding from cells, and after lysis of the cells with a high concentration of chaotropic substances, the concentrations of chaotropic substance and material containing alcohol groups can be adjusted by subsequent addition of a material containing alcohol groups or a mixture of material containing alcohol groups and water or buffer such that a selective binding of the RNA is achieved while the DNA remains in the breakthrough. In the example according to FIG. 1, concentrations of 1.75 M GTC and 30% by volume of ethanol would be selected in order to achieve a separation of RNA from DNA by fractional binding. (Emphasis added.)

Thus, the teachings of the Bastian et al. patent are clearly directed to methods of separating single stranded nucleic acid from double stranded nucleic acid by altering the concentration of alcohol. Notably,

the presence of alcohol in reagents used for binding nucleic acids materially affects the basic characteristics of the methods of binding nucleic acid as proposed by Bastian et al. and therefore would affect the functional capability of the claimed liquid to facilitate binding of nucleic acid to a solid phase. Thus, the phrase "consisting essentially of" as used in the claims presented herein is technically distinct in its meaning that the second liquid employed in the methods of this invention has the basic and novel characteristics of consisting essentially of material selected from the group consisting of: a) a chaotropic agent; b) a chaotropic agent and a chelating agent; c) a chaotropic agent and divalent positive ions; and d) a chaotropic agent, a chelating agent and divalent positive ions, which operate in the claimed methods in the absence of materials such as reagents containing alcohol groups that would materially change the characteristics of the invention, as clearly set forth in the disclosure in Bastian et al.

Furthermore, applicants have demonstrated throughout the disclosure and in the Examples set forth in the instant specification that the basic and novel characteristic of the claimed invention is the successful separation of single and double stranded nucleic acid in the absence of materials containing alcohol groups. Thus, applicants have met the burden as set forth in *In re De Lajarte*, cited by the Examiner, of showing the basic and novel characteristics of the claimed invention and that the introduction of materials containing alcohol groups would materially change these characteristics.

In response to the Examiner's comments on page 4 in the May 17, 2006 Office Action that the present rejection has been maintained because allegedly there is no evidence in the applicants' response "...showing the characteristics of the instant method for separating single stranded nucleic acid from double stranded nucleic acid without or with using alcohol," applicants point out that such a showing is not what is set forth in the MPEP, but rather, according to MPEP § 2111.03 citing *In re De Lajarte*, the burden on the applicants, as the Examiner emphasized in the November 1, 2005 Office Action, is to show that the introduction of additional steps or components would materially change the characteristics of applicants' invention. Applicants have met this burden, as set forth in the response filed February 28, 2006 by demonstrating that the prior art actually provides such evidence.

In response to the Examiner's comments on page 4 in the August 9, 2006 Advisory Action that applicants' arguments that the required burden has been met are not convincing because the instant specification is silent in this regard and that Bastian et al. cannot be relied on, applicants point out that none of the case law cited in MPEP § 2111.03 states that applicants' burden must be met only by what is disclosed in the specification. In particular, a review of *In re Herz* (537 F.2d 549; CCPA 1976), reveals no mention of any such a burden on applicants or how it would be met. The Court in *In re Herz* stated only that there was no evidence that the cited art element in question (a dispersant) would materially effect the

basic and novel characteristics of the applicant's claimed composition and that all evidence was to the contrary, but the Court provided no description of what evidence was or should be considered in reaching this conclusion.

Furthermore, in *PPG Industries v. Guardian Industries* (156 F.3d 1351; Fed. Cir. 1998), a jury was given extrinsic evidence (e.g., deposition testimony) to consider in making a determination of whether a cited art element (iron sulfide) materially affected the characteristics of the patentee's claimed composition, demonstrating that it is not the Court's position that such evidence must come from the specification. In fact, the Court in *PPG Industries* pointed out that the specification was silent on this issue and that it was appropriate for the jury to consider such evidence (see below):

Neither *Atlas Powder v. E.I. duPont de Nemours & Co.* 750 F.2d 1569 (Fed. Cir. 1984) nor *Water Technologies Corp. vs. Calco, Ltd.* 850 F.2d 660 (Fed. Cir. 1988) mention any burden on applicant to demonstrate that the introduction of additional elements would materially change the characteristics of a claimed composition nor how such a burden would be met.

In *AK Steel Corp. v. Sollac* 344 F.3d 1234 (Fed. Cir. 2003), the CAFC found sufficient evidence in the specification to make a determination regarding whether an amount of silicon materially affected the basic and novel properties of the claimed invention directed to an aluminum coating, but made no statement that other evidence could not have been considered or that the evidence had to come from the specification. In fact, the Court in *AK Steel Corp.* reiterated their position in *PPG Industries* that it was proper to allow a jury to determine whether the amounts of iron sulfide in the accused's product had a material effect on the characteristics of the glass because "[t]he district judge properly recognized that the patent is silent about iron sulfide and about what constitutes a material effect on the properties of the glass." (Emphasis added).

Section 2100.3 of the MPEP also cites *In re Janakirama-Rao* 317 F.2d 951 (CCPA 1963) in providing guidance for interpreting "consisting essentially of" in a claim, but a review of this case reveals that the CCPA considered "the whole record," including the disclosure, as well as briefs and arguments, in determining whether the appellant's optical glass, which was claimed as "consisting essentially of" particularly recited elements, was distinguished from the cited art on the basis of this language.

Two other cases cited in the section 2100.3 of the MPEP and specifically mentioned in the Examiner's response in the present application are *In re De Lajarte* 337 F.2d 870 (CCPA 1964) and *Ex parte Hoffman* 12 USPQ2d 1061 (Bd. Pat. App. & Inter. 1989). It is in *In re De Lajarte* that the CCPA sets forth the burden on applicants to show that the introduction of art cited materials (sulfur and carbon) would materially change the characteristics of appellant's claimed composition (insulating glass). The

Court in *In re De Lajarte* considered whether there was "evidence in the record" and whether the appellant had provided a "factual showing" or furnished evidence to meet this burden. Nowhere in *In re De Lajarte* does the Court mention that such evidence had to come from the specification or that "the record" consisted only of the specification.

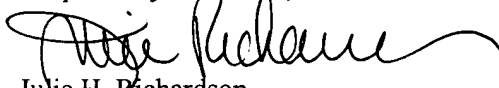
Finally, in *Ex parte Hoffman*, the Board considered both the specification and "the remainder of the record" in evaluating whether the applicants had provided sufficient evidentiary support of their position that certain method steps disclosed in the art were excluded from applicant's claimed methods on the basis that such additional steps would affect the basic and novel characteristics of the applicant's method.

Thus, there is no basis in the case law or elsewhere to support the Examiner's position that Bastian et al. cannot be relied on as evidence that the present applicants have met their burden of showing that the inclusion of alcohol groups in the compositions of the presently claimed invention would materially change the characteristics of the invention. Indeed, the case law supports applicants' position that the evidence applicants have provided is appropriate in meeting this burden and it is apparent from this evidence that this burden has been met and that claims 16-21, 28-31, 39-41 and 43 are not anticipated by Bastian et al.

For at least these reasons, applicants submit that the present application contains clear errors in facts and/or lack of elements needed to support a rejection of the claimed invention as a whole, as noted above and that the pending claims are allowable and applicants therefore request that this application be passed to issuance.

No fee is believed due with this response beyond those already provided herewith. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



Julie H. Richardson
Registration No. 40,142

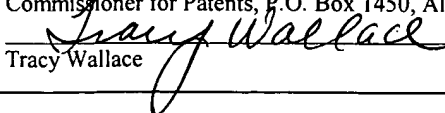
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Tracy Wallace